

### **REMARKS**

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

#### **I. Status of the claims**

Claims 1-3 and 5 are cancelled, and claims 7-20 are withdrawn. Claim 4 is amended to rephrase and simplify the claim, and is consistent with the Examiner's construction of the claim. No new matter is added. After amending the claims as set forth above, claims 4 and 6-21 are pending with claims 4, 6 and 21 under consideration. Claim 4 is the sole independent claim under consideration.

#### **II. Objection to claim 4**

The amendment to claim 4 is respectfully believed to render moot the objections to that claim. Reconsideration and withdrawal of the objection is respectfully sought.

#### **III. Rejection under 35 U.S.C. § 102 and/or § 103**

At pages 4-6 of the Office Action, claims 4, 6 and "12" are rejected as allegedly anticipated or, alternatively, obvious over Sakamoto *et al. Laboratory Investigation* 48: 678-682 (1983) ("Sakamoto"), as evidenced by Ou *et al. Virology* 174: 185-191 (1990) and Miyanochara *et al. J. Virology* 59: 176-180 (1986). As an initial matter, it is respectfully believed that the rejection does not apply to claim 12, which is withdrawn, and was intended to be applied to claim 21, which is under examination. Applicants respectfully traverse the rejection of claims 4, 6 and 21.

Sakamoto uses density gradient centrifugation to isolate two kinds of HBV core particles: low density particles containing DNA (1.19 to 1.23 mg/cm<sup>3</sup>) and high density particles not containing DNA (1.23 to 1.27 mg/cm<sup>3</sup>).

The presently claimed "HBV core-like particles" are HBV incomplete particles lacking DNA. These are distinguishable from Sakamoto's low density particles which contain DNA. The presently claimed HBV core-like particles also differ from Sakamoto's high density core-like particles, as seen in Fig. 3 of the present application. First, the claimed

HBV core-like particles have a particle density *lower* than that of core particles containing DNA, *i.e.*, the reverse relative density of Sakamoto. Second, the claimed particles have an absolute density below  $1.20 \text{ mg/cm}^3$ , as against  $1.23$  to  $1.27 \text{ mg/cm}^3$  for Sakamoto's DNA-free particles. Therefore, the presently claimed particles are distinct from those identified by Sakamoto.

That the presently claimed particles are not HBV core particles is further evidenced by Example 11 of the present specification, in which a peak fraction of HBV core-related antigen does not react in the conventional HBc antigen assay system and the conventional HBe antigen assay system. They are, therefore, antigenically different from HBV core particles.

The presently claimed particles therefore have a different relative and absolute density from the core particles described by Sakamoto, and are antigenically distinguishable from HBV core particles, in general. Sakamoto does not anticipate the claimed invention, therefore. The secondary references do not remedy the defects of Sakamoto and therefore there is no obviousness.

Accordingly, claims 4, 6 and 21 are neither anticipated nor rendered obvious by the cited references. Applicants respectfully believe that the rejection is overcome and request its reconsideration and withdrawal.

**CONCLUSION**

Applicants respectfully believe that all objections and rejections are overcome or rendered moot, and that claims 4, 6 and 21 are immediately allowable. Early confirmation of allowance is respectfully sought.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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